TESTIMONY OF RUSSEL A. BANTHAM,
GENERAL COUNSEL AND SENIOR VICE PRESIDENT,
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
BEFORE THE FOOD AND DRUG ADMINISTRATION

Regulation of OTC Drug Products Hearing
Docket No. 00N-1256

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I am Russel Bantham, General Counsel and Senior Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. Investing over $26 billion this year in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

Prescription drugs discovered and developed by PhRMA members are the source of virtually all major new OTC drugs. PhRMA therefore has a vital interest in the subjects being considered by FDA at this hearing. I will focus my testimony on the matters of greatest concern to PhRMA, and we will file more detailed post-hearing comments in accordance with FDA's notice.

The principal issues that I will address today concern the role of the sponsor in initiating an Rx-OTC switch and the criteria to be applied by FDA in reviewing switch applications.

The Switch Process

The questions presented in the hearing notice suggest that FDA is considering whether it may decide to switch a drug from prescription to nonprescription status without the

participation, or even over the objection, of the holder of the approved NDA for the drug for prescription use. In our view, this would be both unlawful and contrary to the goal of protecting the public health.

Under our regulatory system, FDA reviews applications submitted by sponsors for uses they have presented in their proposed labeling. It is not within FDA's authority to force a manufacturer fundamentally to change the conditions of use of its product from prescription to nonprescription status. The switch of a drug would alter the terms of an approved NDA for a prescription drug by removing the "Rx legend" and changing the labeling from a physician package insert to consumer-oriented directions. Pursuant to section 505(e) of the Federal Food, Drug, and Cosmetic Act, FDA cannot make such changes over the objections of the sponsor without following a notice and hearing process that protects the rights of the NDA holder.

FDA cannot use rulemaking to circumvent this process. While there is a procedure in section 503(b) of the Act, dating back to 1951, for the issuance of so-called "switch regulations," FDA has not used this process since 1971, before the institution of the OTC Drug Review and before the Hatch-Waxman Amendments. The switch regulation procedure was never used, and cannot be used, over the objection of a sponsor to avoid the sponsor's hearing rights under section 505(e). As a matter of both administrative law and procedural due process, FDA could not switch a drug through informal rulemaking without the consent of the holder of the approved NDA that would be changed through the switch.

Forced switches also would violate sponsors' proprietary rights in their safety and effectiveness data. Any switch will be based in substantial part on the demonstrated safety and effectiveness of the underlying prescription drug. The full reports of studies that provide proof of safety and substantial evidence of effectiveness reside in the sponsor's NDA. . They cannot be

relied on by the agency to support regulations or approvals that would allow anyone else to manufacture and sell the drug for either prescription or nonprescription use except to the limited extent permitted under the Hatch-Waxman Amendments.

The current system, under which switches are initiated by NDA sponsors through the submission of new applications or supplements, serves the public health well. Extensive prescription use is essential to the full characterization of a drug's clinical profile in actual use. Moreover, manufacturers have the most comprehensive and detailed knowledge of their drugs, including information bearing on whether a drug is a suitable switch candidate. Taking all of this information into account, manufacturers are in the best position to decide when to begin the switch process and thereby avoid premature switches that could put some members of the public at risk. In addition to poorly serving consumers, the forced-switch approach would unfairly force manufacturers to bear product liability risks associated with OTC use even if they believe that a drug should remain available only by prescription.

Manufacturers also are in the best position to invest in developing the additional data needed to support a switch. Any switch today requires extensive data in addition to what is in the NDA for prescription use. Switches proposed on the basis of conclusory assertions by third parties that are not privy to all data on a drug, and are unwilling or unable to fund the necessary studies to support the switch, should be summarily rejected.

Switch Criteria

Several of the questions in the hearing notice concern the criteria to be used by FDA in evaluating applications to switch drugs from prescription to nonprescription status. We believe that FDA should apply the same approach to these applications that it does to any other

NDA, that is, to evaluate each switch application on its individual merits based on the statutory criteria of safety, effectiveness, and proper labeling.

Thus, for example, nothing in the Act authorizes FDA to declare an indication or a disease state to be exclusively "prescription" or "nonprescription." This question must be addressed in the context of each drug intended to treat or prevent the disease, based on its particular risk-benefit profile and labeling. There is nothing at all incongruous about the simultaneous availability of both prescription and nonprescription drugs for the same condition. This is true today across a wide variety of disease states. Moreover, it promotes sound public health policy by providing consumers the options of both self-treatment where it is appropriate and consultation with a physician and treatment with a prescription drug where that is appropriate. It would not make sense to declare a disease off-limits to prescription drug therapy and thereby discourage both consumers from consulting with their physicians and manufacturers from investing in the development of new products.

As another example, any suggestion that FDA take into account the relative economics of prescription and nonprescription distribution must be rejected. FDA's relevant statutory authority relates exclusively to drug safety, effectiveness, and labeling. The agency has no authority to consider prices or related matters as part of the approval process. FDA certainly should not allow its agenda to be dictated by insurers that are motivated to request switches in order to shift costs from their own prescription drug benefit programs onto consumers. Any change in policy to allow FDA, or third parties, to initiate switches would unnecessarily encumber the drug development process, chilling many areas of research and development and complicating the already difficult considerations that underlie the decision to proceed with drug development.

Conclusion

We commend FDA for holding this hearing on the important subject of Rx-OTC switches and other aspects of nonprescription drug regulation. FDA should retain its existing policy of making switch decisions through the evaluation of NDAs and supplements filed by manufacturers, based on an individual assessment of the safety and effectiveness data and proposed labeling for each specific switch candidate. This approach is the one that FDA must follow in accordance with the law. It also best protects the safety of consumers. It ensures that consumers will have the widest possible array of treatment options, both prescription and OTC. And it fosters an environment that is conducive to investment in drug research and development. Only through continued research and development will consumers have more treatment options – both prescription and OTC – in the future.